COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENVIRONMENTAL AFFAIRS
**DEPARTMENT OF ENVIRONMENTAL PROTECTION**
**WESTERN REGIONAL OFFICE**
436 Dwight Street • Springfield, Massachusetts 01103 • (413) 784-1100

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September 30, 2003

Ecological Risk Assessment Peer Review Panel
c/o Ms. Alison Wolfe
MNG Center at SRA
2801 Clarendon Boulevard, Suite 100
Arlington, Virginia 22201

Re: The Massachusetts Department of Environmental Protection's Technical Review Comments on EPA's July 2003 *Ecological Risk Assessment for General Electric (GE)/Housatonic River Site Rest of the River*

Dear Peer Review Panel Members:

The Department of Environmental Protection (DEP) has reviewed the report titled *Ecological Risk Assessment for General Electric (GE)/Housatonic River Site Rest of the River* (Ecological Risk Assessment), prepared by Weston Solutions, Inc. for the U.S. Environmental Protection Agency (EPA), dated July 2003. DEP understands that this monumental document represents the culmination of five years of intensive and comprehensive fieldwork, and thoughtful and detailed debate and deliberation by a dedicated work group. Overall, DEP concurs many of the methodologies employed and the conclusions reached in the risk assessment, but is providing some recommendations as to how the risk assessment might be improved.

This letter summarizes comments by Nancy Bettinger and Thomas Angus, risk assessors from our Office of Research and Standards, who performed as complete a review of the document as time constraints would allow and provided risk assessment expertise on behalf of the project managers in the Bureau of Waste Site Cleanup Western Regional Office Special Projects Unit.

DEP offers the following comments for the Peer Review Panel's consideration. The majority of the comments in this memorandum focus on the Appendices. The Appendices detail the measurements of effects and describe the evaluation of the major assessment endpoints. They include:

- Appendix D – Community Structure, Survival, Growth and Reproduction of Benthic Invertebrates
- Appendix E – Community Condition, Survival, Reproduction, Development and Maturation of Amphibians
- Appendix F – Survival, Growth and Reproduction of Fish
- Appendix G – Survival, Growth and Reproduction of Insectivorous Birds
- Appendix I – Survival, Growth and Reproduction of Piscivorous Mammals

In addition, DEP has reviewed and commented on the Risk Summary. Some of DEP's comments relate to risk assessment decisions that have had an effect on the outcome of the risk assessment. Other comments relate to aspects of the risk characterization that would not change a result, but nevertheless appear to be inconsistent, in principle, with current regulatory risk assessment guidance or practice.

## I. GENERAL COMMENT ON STUDIES CONDUCTED BY GENERAL ELECTRIC

EPA carefully planned and conducted numerous field and laboratory studies to support the assessment endpoints for the ecological risk assessment. The details of these studies were presented in *Final Supplemental Investigation Work Plan for the Lower Housatonic River, February 22, 2000*, prepared by Roy F. Weston, Inc., for the U.S. Army Corps of Engineers, North Atlantic Division, New England District. In their February 2000 work plan, EPA had carefully established assessment and measurement endpoints. Biological field studies in EPA's work plan were designed to evaluate measurement endpoints in a weight of evidence approach.

At a May 3, 2001 meeting, GE presented some biological field studies that they were presently conducting on its own, independently of the EPA's studies and the ecological risk assessment. GE's studies were conducted without approval from EPA or DEP. For example, GE's robin field study, GE's belted kingfisher field study, and GE's shrew population survey were not originally part of EPA's risk assessment work plan and DEP was not given an opportunity to comment on the study design or the plan for incorporating these results of these studies into the risk assessment. EPA has made a good faith effort to fully incorporate these studies into the appropriate weight-of-evidence evaluations. Nevertheless, DEP does not consider the results of GE's studies as valid, independent lines of evidence. The reasons for this opinion vary for different studies and include technical flaws, redundancy and irrelevance to the niche on which the assessment endpoint is focused. DEP recommends excluding the results of GE's field studies as independent lines of evidence, but including them as supportive or contradictory information in the risk characterization section and/or the uncertainty analysis.

## II. COMMENTS ON THE RISK SUMMARY

DEP's conclusions about each assessment endpoint are discussed below.

**Benthic Invertebrates**

Laboratory toxicity tests and sediment benchmarks provide strong evidence that concentrations of polychlorinated biphenyls (PCBs) and Toxic Equivalence (TEQ) present a high risk to benthic invertebrates.

**Amphibians**

Sediment toxicity studies in late larval/metamorph life stage wood frogs provide strong evidence of high risk. Sediment toxicity studies in leopard frog larval, late larval/metamorph, and adult life stages present strong evidence of a high risk.

**Fish Community**

DEP agrees with the conclusion that the risks are low to moderate for mortality of adult fish. However, DEP does not believe that mortality to adult fish should be the primary measure of risk to the fish community. A high probability of impacts to reproduction and development are predicted throughout the primary study area. DEP considers these more sensitive effects to reproduction and development to be important endpoints, because they contribute to deleterious effects on population or structure or community structure. DEP, therefore, recommends that the ecological risk assessment make conclusions about ecological risk to the fish community based on these more sensitive endpoints, in addition to mortality.

**Insectivorous Birds**

DEP disagrees with the conclusion that the risk to insectivorous birds is low. DEP believes the risk to insectivorous birds is moderate and the rationale is documented below.

The results of GE's assessment of robins (Henning 2002) have been included as a measure of effects for the insectivorous bird assessment endpoint in this revision. Previously, this endpoint focused on tree swallows. Although tree swallows and robins are both insectivorous birds, they should not be evaluated in the same assessment endpoint because they use different habitats and therefore occupy different niches. Tree swallows feed primarily on emergent aquatic insects while robins feed primarily on terrestrial upland insects. Given the lower concentrations of PCBs in upland areas compared with sediment, robins will be exposed to relatively low levels of PCBs and are less likely to exhibit effects of PCB exposure. Because of these differences in exposures, it is inappropriate to combine tree swallows and robins in a weight-of-evidence approach. DEP recommends adding a separate assessment endpoint for terrestrial insectivorous birds.

Further, as discussed in the risk assessment, studies in the scientific literature suggest that tree swallows are relatively insensitive to total PCBs (tPCBs) compared to other bird species. Because of this relative insensitivity, studies in tree swallows do not represent a good surrogate for other species. A lack of effects in tree swallows should not be interpreted to mean that other potentially more sensitive species would be protected. Based on the lack of sensitivity of tree swallows to PCBs, DEP believes that the weighting value for the tree swallow study should be changed from "high" to "medium". When the medium-weight, low-risk tree swallow study is

combined with the medium-weight, high-risk exposure modeling, the overall conclusion would be moderate risk.

**Piscivorous Birds**

There were many problems with GE's belted kingfisher study (Henning 2002) that cause it to be a weak study. Sections H.4.2.1 and H.4.2.2 of the Ecological Risk Assessment documents the weaknesses of the study, including:

- The total daily intake calculation does not result in a dose gradient necessary to evaluate a dose-response relationship for piscivorous bird consuming Housatonic River fish due to fish sampling location resolution and fish mobility throughout life stages.

- The diet calculation in the study did not assume prey proportions typically consumed by kingfishers.

- Only nine belted kingfisher burrows were monitored during the study, and three of these were depredated before the fledging date. Three of the remaining six nests were outside the primary study area, and a significant portion of the diet for these birds may have come from outside the study area. The small number of kingfisher burrows creates a statistically weak study.

- The range of estimated total daily intakes in the primary study area was narrow, and provided an insufficient basis on which to derive a dose-response relationship.

Based on these factors, DEP recommends excluding the GE kingfisher field study as a quantitative line of evidence in the weight of evidence evaluation, and instead including it as a supplementary study discussed qualitatively in the risk characterization and uncertainty sections. The remaining line of evidence, modeled exposure and effects to the kingfisher and the osprey, indicated a high magnitude of risk to both the kingfisher and the osprey from exposure to tPCBs. DEP recommends focusing on these results in the risk characterization.

**Piscivorous Mammals**

DEP agrees with EPA's conclusion that the risk of harm to piscivorous mammals is high.

**Omnivorous and Carnivorous Mammals**

DEP agrees that based on the lines of evidence, the risk of harm to omnivorous and carnivorous mammals is moderate to high. However, DEP disagrees with EPA's decision to use the results of the GE-sponsored Boonstra (2002) shrew population survey. The EPA risk assessment documents numerous problems in the GE-sponsored shrew population survey. These problems are listed below:

- No reference location was used because there were no suitable areas with similar vegetation types. Instead, results from the literature were used for comparison with the results from the study. The lack of a site-specific reference area introduces considerable uncertainty in the study findings.

- The six site areas used for trapping in the study varied in habitat quality. Without habitat and microhabitat data at the six trapping locations, it is difficult to tell if differences in habitat explain variation in population parameters between the six locations.
- Flooding during the spring season limited the number of trapping sessions and some of the statistical analyses could only be conducted for three of the six locations.

- The population estimator assumed no mortality, and no immigration or emigration during the sampling period. This is unlikely to be realistic.

- The Boonstra (2002) estimates of tPCB concentrations in soil appear to be in error. Several factors may have contributed to this error including: (1) Boonstra (2002) included samples from areas that are not shrew habitat (e.g., sediment samples from aquatic areas); (2) the Boonstra spatial-weighting approach relied solely on data internal to the grids – with small sample sizes in some of the grids, this likely produced poor estimates of the spatially-weighted arithmetic means; and, (3) some soil samples used in the analyses do not exist in the Housatonic River database (which includes historical and recent data from both EPA and GE) or soil samples were not included in the Boonstra (2002) study that are in the database.

DEP concurs with EPA on the problems in the Boonstra (2002) survey.

EPA took the further step of developing a supplemental analyses of the Boonstra (2002) data. The results provide evidence of a significant relationship between spatially-weighted mean concentrations of tPCBs and survival of shrews, although the relationship was not strong. EPA then combines the results of their supplemental analyses with the results reported by GE, and then uses the combined results in the weight-of-evidence analysis. Because of the problems in the Boonstra study, DEP recommends excluding the GE results from the weight of evidence evaluation, although it may be appropriate to include the data from the supplemental analysis if EPA has sufficient confidence in the underlying study.

**Threatened and Endangered Species**

DEP agrees that, based on the lines of evidence, the risk of harm is moderate to high for selected threatened and endangered bird and mammal species.

## III. COMMENTS ON APPENDIX D: BENTHIC INVERTEBRATES

DEP agrees with the overall conclusion that the ecological risk is high for benthic invertebrates. DEP had previously commented on the sediment toxicity studies but not the benthic invertebrate appendix as a whole. DEP's previous comments on the sediment toxicity studies were addressed in the current version of the benthic invertebrate appendix.

## IV. COMMENTS ON APPENDIX E: AMPHIBIANS

### Reproductive and Developmental Studies in Leopard Frogs

The risk assessment should discuss possible reasons why leopard frogs were not found at any of the three reference locations. Frogs obtained from a laboratory supplier were used in place of field-collected reference organisms. The *R. pipiens* report from Fort Environmental Laboratories (2002) cites adverse weather conditions and seasonal factors as likely contributing to the lack of frogs in reference areas. These explanations should be reiterated and elaborated upon in the text of the risk assessment. It is unclear why additional reference locations were not chosen and why frogs from a commercial supplier were used as a reference. The report should explain why alternate reference locations were not chosen.

Section E.5 of the risk assessment (Sources of Uncertainty) does not contain an adequate discussion of the uncertainties introduced by the reference comparison. The lack of reference location data combined with the lack of a clear dose-response relationship with PCB concentrations contribute a high degree of uncertainty to conclusions about ecological risks to leopard frogs. Tissue concentrations in organisms at sampling locations are not directly comparable to tissue samples from laboratory organisms. Reference frogs from a natural environment may contain a background body burden of contaminants that the commercially supplied organisms would not. The report should discuss the uncertainties that are introduced into the risk assessment by using leopard frog tissues from a commercial supplier rather than reference locations.

### Reproductive and Developmental Studies in Wood Frogs

Since there were more than 60 amphibian breeding sites documented in the Primary Study Area, the risk assessment should explain why an additional vernal pool was not added when egg masses were unavailable in one of the contaminated vernal pools

The text should provide further discussion of why the reference tissue concentration from WML-1 was considered an anomaly and was not included in the HQ calculations. In general, large false positive results from sampling and analysis variability are not likely, and high results should not be rejected simply because they are unexpected.

### Weight-of-Evidence Approach

DEP concurs with the weight-of-evidence approach used in the assessment of amphibians. The weights assigned to various lines of evidence are reasonable and the support document's conclusion that a significant risk is posed to frog species in the Primary Study Area.

## IV. COMMENTS ON APPENDIX F: FISH

### General Comments on the Phase I and Phase II Fish Toxicity Studies

The risk assessment should discuss the following issues related to test species in the Phase I and Phase II Fish Toxicity Studies:

- Selection process for the largemouth bass and bluegill chosen as the test species in the Phase I study (i.e., the report should discuss any consideration given to choosing bottom-feeding fish that have greater contact with sediment).

- Selection process for Phase II species. The report should indicate how rainbow trout and medaka, in addition to largemouth bass, were chosen as test species for the Phase II egg injection study. The report should discuss if the Housatonic River is capable of supporting a reproducing population of a coldwater species such as the rainbow trout.

The risk assessment should discuss the following issues related to study and reference areas:

- Selection process for study and reference areas. The report should explain whether a range of contaminant concentrations is a criterion for study area selection.

- Ability to generate a dose-response curve that can be used to draw conclusions about reproductive effects in areas with lower contamination.

- Information to be generated on extent of effects in the river, or potential cleanup levels, if possible.

The risk assessment should discuss potential confounding factors in the Phase I and II fish studies, including the following issues:

- The study does not take into account the possible synergistic effects of planar halogenated hydrocarbons analyzed for in the study and other pollutants, such as PAHs, and metals that are present in the Primary Study Area. The risk assessment should discuss the scientific literature for the endpoints to be evaluated and confirm that these endpoints are specific to the contaminants evaluated in the study.

- The studies assume that the dominant exposure pathway for larvae is maternal exposure. The risk assessment should discuss the mechanism of maternal transport of contaminants to eggs and the relative importance of this pathway compared to other exposure pathways, such as direct contact with contaminated surface water and sediment. The risk assessment should also indicate what additional impacts to larvae could occur if they were hatched and raised in contact with Housatonic River surface water and sediment.

- The risk assessment should discuss the potential for depuration of chemical contaminants and present information from the literature on depuration rates of the contaminants of interest. Adult largemouth bass and offspring were removed from contaminated areas of the Housatonic River and thereafter removed from contact with contamination during transport and execution of the study. The risk assessment should discuss contaminant depuration times from the literature, the length of time that fish were out of contact with contaminated media, and the potential for underestimating body burden due to depuration. The risk assessment should discuss any available information on whole body versus ovary depuration rates, and any potential effects of depuration on maternal transfer.

The Phase I and Phase II studies are very useful for the reproductive endpoints they measure. However, the studies did not evaluate decreased competitive fitness, or decreased genetic diversity in fish populations due to pollution stresses. The risk assessment should discuss any consideration given to these endpoints, and what can be inferred about them based on the results of the Phase I and II studies.

### Comments Specific to the Bluegill Study

The risk assessment should discuss the bluegill study. The Phase I fish study design called for the use of two species in testing, largemouth bass and bluegills. Both species were collected from the Housatonic River and transported to the laboratory, but bluegill spawning at the laboratory was unsuccessful. The risk assessment should provide a summary of difficulties encountered in the bluegill study, including:

- The likely reasons for failure of the study. The study report stated that the most probable reason for failure of bluegill spawning was the long holding time in circular tanks, possibly disturbing the process of gonad maturation. However, the risk assessment does not discuss any reasons for the failure of this study.

- Whether it is typical for bluegills to have difficulty spawning after two months in a holding tank and if this holding time was longer than originally anticipated due to delays in bass spawning.

- Whether the *Ichthyopthirius* infestation that may have affected spawning was also present in bass and if it could have affected reproductive success in bass.

- Whether it is possible that contamination effects could have resulted in the reproductive failure observed in the bluegills and whether other data collected support or refute this hypothesis.

- Whether fish stressed by PCBs are particularly prone to *Ichthyopthirius* infestation and if these parasites occur in the reference area or are a potential confounding factor.

- How the failure of the spawning study may affect evaluation of the largemouth bass study. Any possible implications should be discussed.

## VI. COMMENTS ON APPENDIX G: INSECTIVOROUS BIRDS

### Microexposure Model for Tree Swallows

The risk assessment uses a microexposure model to calculate tree swallow tissue concentrations. The microexposure model results were not used to estimate risks, because the results were similar to measured tissue concentrations. Measured tissue concentrations are available for tree swallows and are preferable to modeled data. DEP believes that the tissue modeling should be eliminated from the risk assessment.

### Risk Estimates for Tree Swallows

The risk estimates calculated in the risk assessment do not reflect the magnitude of risk because a dose-response relationship was not available from the scientific literature. The upper and lower thresholds of toxicity ranges used in the risk assessment come from different papers. The difference in upper and lower values is due to differences between the studies, and does not correlate to a dose-response relationship. Nevertheless, they are used to demarcate low and high risks from indeterminate risks.

### Direct Bioaccumulation Model

Section G.2.1.3.2. discusses body weight data for the tree swallow. The report discusses variations in tree swallow body weight based on food availability and season. Tree swallow body weights fluctuate over the course of the year and are correlated with the availability of food, which is different for different seasons. Since the modeling effort is attempting to evaluate changes in body weight over just the breeding season, and not the whole year, the body weight distribution incorporated into the model should only represent the breeding season.

### Insensitivity of Tree Swallows to PCBs

The previous draft of the ecological risk assessment had stated that studies in the scientific literature suggest that tree swallows are relatively insensitive to tPCBs compared to other bird species. A threshold range for reproductive effects of 0.12 to 7.0 mg/kg bw/d was developed using studies from the literature and based on reproductive studies in white leghorn chickens and American kestrels, respectively. The report should include specific discussion of the relative insensitivity of tree swallows to tPCBs compared to other insectivorous birds. Tree swallows were chosen as a surrogate for other insectivorous bird species. The risk assessment should discuss the implications of the relative insensitivity of tree swallows. Other insectivorous birds may potentially be at risk at environmental levels that do not produce effects in tree swallows.

### Weight-of-Evidence Analysis

For evaluating the correlation of the stressor to the response, the weight-of-evidence analysis considers only studies used in the development of upper and lower thresholds for tPCBs and TEQs. DEP guidance states: "To evaluate the correlation of the stressor to the response, the risk assessor should consider the number of studies of good quality that show a causal or correlative relationship between endpoints. The risk assessor should also consider whether a statistical correlation has been demonstrated." The intent of this guidance is to affirm that evidence from previous studies could be considered to demonstrate a dose-response relationship; a site-specific demonstration of a dose-response relationship is not necessary if the correlation between the stressor and effect of concern has been adequately evaluated in previous studies.

## VII. COMMENTS ON APPENDIX I: PISCIVOROUS MAMMALS

Overall, DEP found the assessment of the piscivorous mammals endpoint to be comprehensive and cogent. DEP reviewed the piscivorous mammals section of the Ecological Risk Assessment in addition to Appendix I. Revisions to Appendix I have improved the clarity

of the report, but DEP still has a number of concerns that are summarized in the sections that follow.

## General Comments

DEP has two major areas of concern about the piscivorous mammals assessment. The first is the question of whether the results of the Monte Carlo analysis truly represented variability, or whether they reflect a combination of variability and uncertainty. The second area of concern is the weight of evidence analysis, specifically some of the decisions about assigning weights to different measurements and weights and integrating lines of evidence. Detailed comments on the piscivorous mammals assessment follow.

## Assessment of Risk from Site-specific Dietary Exposure Estimates and Toxicity Values from the Literature

### Proportions of Dietary Items

The range of values used to represent the proportion of each dietary item appears to include values from all available studies. The text states: ". . . minimum, mean and maximum values were specified for each dietary item using the means and ranges described above. The minimum, mean and maximum were then included as a distribution-free statement in RiskCalc. The results bound all possible distributions, given the specified minimum, mean and maximum values specified for the dietary items." From this, it appears that the Monte Carlo analysis treats the range of proportions of each dietary item independently from the ranges of other items. In fact these proportions are not independent. In the wild, as the proportion of fish increases, the proportion of other components must decrease. No individual mink's diet would contain both the highest reported proportion of fish and the highest reported proportion of invertebrates.

In addition to the problem of independence among proportions, DEP is concerned about including data from different studies conducted in different environments. It appears that the ranges used in the Monte Carlo analysis incorporate both individual variability and uncertainty about dietary composition. As mentioned previously, if the Monte Carlo analysis is meant to assess exposure variability, the input distributions and ranges should reflect primarily variability, not uncertainty.

Assuming DEP's interpretation of the report is correct, DEP recommends revising the assessment to use either point estimates of proportions or a simpler approach to incorporating ranges of proportions in place of distributions of proportions.

### Mink Food Intake Rate

In the model (Equation 2) for estimating the food intake rate, the numerator is a distribution representing the variability in the free metabolic rate (daily energy requirement) among individual animals, and the denominator appears to be a distribution representing the energy content in variously composed diets. DEP has several concerns about the models for estimating the free metabolic rate and the food intake rate:

- Although a proportion factor is included in the list of terms defined for Equation 2, it is not actually included in the equation. This discrepancy also occurs in the food intake rate equation for otter. The list of terms should be consistent with those used in the equation.

- It is unclear how the prey-specific PCB concentrations are incorporated into this model.

- The model (Equation 3) for estimating free metabolic rate (FMR) from the body weight includes a slope term (*a*) and a power term (*b*). The distributions used for these terms appear to represent uncertainty about the FMR estimate, not variability with population. The report states: "For the Monte Carlo and probability bounds analysis, FMR was estimated using a probabilistic approach where distributions of the input variables (body weight, *a*, *b*) were used rather than point estimates. The slope (*a*) and power (*b*) distributions were based on the error statistics reported in Nagy et al. (1999), assuming an underlying normal distribution for each." Thus it appears that uncertainty is incorporated into the input distributions for the Monte Carlo analysis, and that the output does not represent exposure variability, contrary to statements made in previous sections of the report.

Since the approach used to evaluate otter exposures was similar, these comments apply to that portion of the assessment as well.

<u>PCB Concentrations in Prey</u>

- In describing the fish concentrations used in the assessment, the bases of the concentrations are not explained. The report should specify whether the fish concentrations are based on wet or dry weight, skin on or skin off and whole body or filet.

- Concentration estimates of PCBs in waterfowl are uncertain because only breast and liver tissues were analyzed; offal concentrations were not determined. Low, moderate and high whole body concentration estimates were developed for each bird analyzed by assuming that offal concentration was zero, equal to the breast concentration and equal to the liver concentration respectively. The text states: ". . . a triangular distribution was used in the Monte Carlo analysis to capture the uncertainty about the estimate of the measure of centrality. The Land H-statistic was used to determine the lower and upper 95% confidence limits on the mean concentrations for the low, moderate and the high concentration estimates." DEP has several concerns about the approach described:

    - The triangular distribution for total body concentration described above is likely to overestimate the uncertainty about the prey concentration, because the minimum estimate represents an offal concentration of zero and the maximum estimate represents and offal concentration equal to the liver concentration. The offal concentration would not be zero if any PCBs were detected in the liver or breast, nor would it be as high as the liver concentration. The offal concentration is more likely to lie between the breast and liver concentration. An effort should be made to identify data in the literature that could be used to estimate the offal concentration from the liver and/or breast concentration of each bird.

- The triangular distribution described represents lack of knowledge about whole body concentrations in a prey item, not variability in the exposure of individuals or groups of piscivorous mammals. If this distribution is used as an input into the Monte Carlo exposure assessment, then the output cannot be interpreted as an exposure distribution. As stated previously, the incorporation of a distribution representing lack of knowledge about an exposure factor is inconsistent with the way the report states that the Monte Carlo analysis is used.

Developing of Effects Endpoints for Characterizing Risk

In comments on previous drafts, DEP raised a number of concerns about this section of Appendix I. In the current Public Comment Draft of the risk assessment, this section has been omitted from Appendix I. In its place, the effects endpoints are addressed very briefly in Sections 9.4.3.1 and 9.4.3.2 of the main body of the risk assessment. The level of detail is insufficient, and supporting documentation is not referenced.

Comparison of Estimated Exposures to Laboratory-derived Effects.

This section, which describes the comparison of estimated mink and otter exposures in the Primary Study Area with dose-response curves (for total PCB) and threshold values (for TEQs) should be more detailed. DEP has several specific concerns about the proposed exposure distributions and effects metrics:

- The report proposes to integrate the exposure distribution developed for each species and exposure area with the PCB dose-response curve developed from studies reported in the literature, and to categorize the outcomes as low, indeterminate or high risk, using the following criteria:
  - If the probability of 10% or greater effect was less than 20%, then the risk to piscivorous mammals was low.
  - If the probability of 20% or greater effect was greater than 50%, then the risk was high.
  - All other outcomes were considered to have indeterminate risk.
- DEP has several concerns about this proposal:
  - The set of criteria above do not define a “no risk” or insignificant risk category. Thus, all outcomes are taken as positive evidence of risk or harm, with varying levels of severity. Criteria should be established to define a “no significant risk” category.
  - These criteria leave a large gap between exposure distributions that would be deemed low risk and conditions that would be considered a high risk. The family of possible exposure distributions that would be judged to pose an “indeterminate risk” appears to be fairly large. For example, if the probability of a 90% effect were 40%, the risk would be judged indeterminate, inappropriately in our opinion.

Since these criteria are intended to characterize risk, the "indeterminate" category is not helpful. The criteria should be set so that any possible exposure distribution would fall into a meaningful category, i.e., either no risk or low, medium or high risk.

- These criteria above are expressed in terms of "probability of *x* % or greater effect." The "probability of effect" relates to the exposure distribution resulting from the Monte Carlo analysis. If that distribution truly represents exposure variability, it provides proportions, or percentiles, of animals expected to receive various doses, not probabilities. Referring to these proportions as probabilities is misleading, and consideration should be given to revising the wording. For example, it may be more accurate to state the first criterion above as follows: "If the proportion of the population exposed to a dose equal to or greater than the 10% effect level is less than 20%, then the risk . . . is low."

- Regarding the comparison of threshold values to TEQ exposure distributions, DEP has the following comments:

  - Similar to the criteria for comparison to dose-response curves, the criteria for comparison to threshold values do not define a "no significant risk" category. The set of criteria should be revised to include such a category.

  - The upper and lower thresholds are not defined in terms of an expected level of effects, so it is impossible for the reviewer to know the implications of a given probability of exceeding either threshold. The thresholds should be clearly defined, and the basis for them should be discussed.

  - The criteria should be set so that all cases that are not "no risk" fall into a low, medium or high risk category. The indeterminate category is not useful as an indicator of magnitude of risk. It may however be useful as a category between "risk" and "no risk".

**Weight-of-Evidence Analysis**

A number of previous comments have implications for the weight-of-evidence analysis but will not be repeated here. DEP's comments specific to the risk characterization section follow:

- In evaluating the strength of each measurement with respect to the stressor-response correlation, this assessment, like most weight-of-evidence evaluations we have reviewed, considers only whether the measurement itself shows a clear dose-response relationship. It does not consider evidence from previous scientific studies that demonstrate a correlation between exposure to PCBs and the severity of the effect being evaluated. For example, the "modeled exposure and effects" line of evidence for TEQ concentrations was given a moderate weight rather than a high weight because a threshold range was used to characterize risk, and a dose-response curve was not developed for this assessment.

Although this is consistent with the way most risk assessors have applied the weight-of-evidence approach, it is not consistent with DEP guidance, which states: "To evaluate the correlation of the stressor to the response, the risk assessor should consider the number of studies of good quality that show a causal or correlative relationship between endpoints. The risk assessor should also consider whether a statistical correlation has been demonstrated." The intent of the DEP guidance is to affirm that evidence from previous studies could be considered to demonstrate a dose-response relationship; a site-specific demonstration of a dose-response relationship is not necessary if the correlation between the stressor and effect of concern has been adequately evaluated in previous studies.

- The biological surveys were assigned a low-medium value for stressor-response correlation in the weight-of-evidence evaluation. If data from previous studies are considered as evidence of a stressor-response relationship, as recommended in the preceding comment, this value might be higher.

- Only the EPA field survey results should be included as an independent line of evidence. The GE field survey results should be excluded because the measurement is essentially redundant with EPA's field survey, and because EPA has raised a number of questions about the validity of GE's survey.

DEP appreciates the opportunity to present the above review comments to the panel for its consideration.

Sincerely,

Susan J. Steenstrup
Project Coordinator, Special Projects
Bureau of Waste Site Cleanup

SJS/sjs
Attachment

cc: Susan Svirsky, EPA New England Region
Bryan Olson, EPA New England Region
Michael Carroll, GE
Andy Silfer, GE
Kevin Mooney, GE
Rod McLaren, Esq., GE
James R. Bieke, Esq., Shea & Gardner
Anna Symington, Deputy Regional Director, BWSC, DEP WERO *(electronic copy)*
Robert Bell, Regional Counsel, DEP WERO *(electronic copy)*
Thomas Angus, DEP ORS *(electronic copy)*
Nancy Bettinger, DEP ORS *(electronic copy)*
Susan Peterson, CT DEP
Commissioner of Health, City of Pittsfield
Boards of Health: Lenox, Lee, Stockbridge, Great Barrington, Sheffield

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